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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,248	02/13/2001	Robert Amson	065691/0209	2805

23533 7590 07/16/2002

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EXAMINER

SCHULTZ, JAMES

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 07/16/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/762,248

Applicant(s)

AMSON ET AL.

Examiner

James D. Schultz

Art Unit

1635

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 11-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

Claims 14-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims of the above invention are drawn to methods of screening for compounds with "memory restoring activity". The language comprising "memory restoring" is vague and indefinite. One could not know whether the method seeks compounds that restore specific memories that were once held but were then lost over time, or if such compounds would restore one's capacity to formulate new memories, or further if said compounds would enhance the overall number or quality of memories that a person holds on to over time.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Art Unit: 1635

The invention of the above claims is drawn to methods of screening for compounds that either inhibit anxiety or restore memory comprising administering a compound to a p53 deficient animal and determining if said compound restores the behavior, wherein said animal is a mouse, or wherein said p53 deficiency is present in both alleles.

The factors listed below have been considered in the analysis of enablement:

- (A) The breadth of the claims;
- (B) The nature of the invention;
- (C) The state of the prior art;
- (D) The level of one of ordinary skill;
- (E) The level of predictability in the art;
- (F) The amount of direction provided by the inventor;
- (G) The existence of working examples; and
- (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

In order for the claimed methods to be enabled, one skilled in the art must be reasonably certain that by practicing the steps of the method, one will reach the outcome as claimed. The specification as filed does not provide any guidance or examples that would enable one skilled in the art to employ the methods as presently claimed with any certainty that they will result in finding any compounds with the claimed activities. Further, the prior art is silent on whether any compounds exist at all that can overcome the loss of function that the p53 mutations introduced. The lack of guidance or examples from either the specification or the prior art thus requires the user to engage in undue trial and error experimentation with no indication as to whether success will be possible.

There is a high level of unpredictability inherent in using a p53 knockout animal as a model to screen for compounds that modulate anxiety or memory. Much of this unpredictability is due to the virtual lack of knowledge as to how p53 mutations contribute to such behavioral deficits. While it is known that p53 is a tumor suppressor gene that acts by way of repairing DNA mutations that randomly develop in the lifecycle of the cell, and much study has been accorded this protein due to its prominent role in oncogenesis, p53 has no established relationship to anxiety or memory disorders described heretofore.

While the loss of p53 activity is presumably responsible for said introducing said behavioral deficits, no compound has yet been identified in the prior art that restores p53 activity. Despite the fact that p53 mutations are the most common gene mutation found in most cancer types, decades of research have yet to identify a compound capable of restoring lost p53 function. p53 plays a prominent role that in the cell cycle, programmed cell death, and in repairing DNA mutations, and is distributed widely; knocking out p53 activity would likely have untold consequences on cellular physiology as related to these behaviors. It is not at all clear that any compound to be screened will ever work in p53 deficient animals to correct the defect that its mutation introduced. In the absence of working examples from the specification or the prior art that demonstrate that p53 deficient animals are capable of having these behaviors restored by any means, let alone by an exogenously applied compound, the results of using said method as outlined would have substantial unpredictability. One of skill in the art would not be apprised as to whether said deficits can be overcome by any compound at all. Accordingly, use of this

Art Unit: 1635

animal model to screen for compounds with the claimed activities carries with it a high level of unpredictability.

Thus, although the specification prophetically considers and discloses general methodologies of using p53 deficient animals to screen for compounds that inhibit anxiety or restore memory, such a disclosure would not be considered enabling. Since no working examples are provided, either from the specification or the prior art, the use of a gene knockout model system to find compounds capable of modulating healthy animals is highly unpredictable as outlined above.

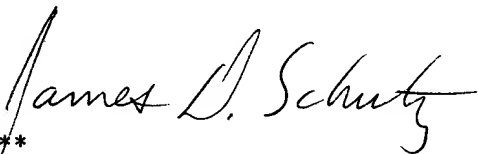
Finally, the quantity of experimentation required to practice the invention as claimed would require establishing that said behaviors are at least capable of being overcome to some degree by a compound. Since the specification fails to provide any guidance for the successful use of a compound that works in said method and since no known mechanism can provide any degree of certainty that the method steps will work as claimed, one of ordinary skill in the art would be unable to practice the invention without engaging in undue trial and error experimentation as presented in the specification.

Conclusion

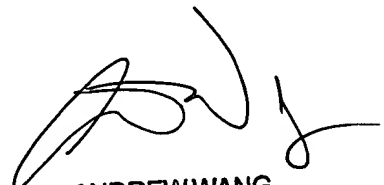
Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Schultz whose telephone number is 703-308-9355. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



July 12, 2002


ANDREW WANG
PRIMARY EXAMINER